REMARKS

Examiner Snow is thanked for withdrawing several rejections regarding the pending claims. Reconsideration of the rejections in the current Office Action is in light of the following is respectfully requested.

The Examiner is Requested to Withdraw Finality

The current Office Action alleged as to claim 19 that "the elected embodiment . . . is not capable of being an expandable motion preserving device," and on that basis claim 19 was not enabled. The prior office action suggested non-enablement of claim 19 from the question "how does the elected embodiment maintain disc space after removing the expandable element?" The prior rejection was grounded in maintaining disc space, while the new rejection relied on the new ground of whether a device can be an expandable motion preserving device.

Because the current Office Action alleged that a different part of claim 19 is non-enabled, it provided a new ground for rejection. No amendments were made to claim 19 in the last office action, and therefore the new rejection was not necessitated by an amendment. In *In re Waymouth*, 179 USPQ 627, 628-29 (CCPA 1973), the claim at issue recited a certain amount of an ingredient, and the examiner rejected the claim alleging that the ingredient itself was new matter. The Board found support for the presence of the ingredient, but not for the recited amount of the ingredient. The Court ruled that the new matter rejection for the amount was a new ground for rejection. Likewise, in this case the prior rejection asserted non-enablement of one part of the claim, and the present rejection has a new allegation of a different aspect of the claim alleged to be non-enabled. The new rejection is not merely a change in discussion of or

reasoning concerning a reference, but requires new and different evidence. Applicant has not had an opportunity to react to this ground of rejection.

The Claims are Properly Enabled

The Office Action alleged that "the elected embodiment shown in figures 1 and 4A is not capable of being an expandable motion preserving device." With no other evidence or analysis, independent claims 1 and 19 and the rest of the claims were deemed non-enabled. For the following reasons, the Examiner is requested to reconsider and withdraw this rejection.

No Prima Facie Case of Non-Enablement Has Been Made

"In order to make a rejection, the examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention," by giving reasoned explanation as to why the claim scope is not adequately enabled.. MPEP 2164.04 (*citing In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). "A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement . . . unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." MPEP 2164.04.

The Examiner has not provided an explanation of alleged non-enablement, only the conclusory statement noted above. There is no reasoning provided to "doubt the objective truth"

of the specification that describes the claimed methods. Per the MPEP and case law, this enablement rejection should be withdrawn for lack of support.

The Entire Specification Is Relevant to Enablement, Not Just One Structure

The *Wright* opinion and MPEP 2164.04 also make plain that the focus of enablement is on the "claimed invention," that is, "the subject matter sought to be patented." The subject matter of claim 1 is a method for intervertebral stabilization including particular actions, and the subject matter of claim 19 is a method of intervertebral distraction including particular actions. The Examiner's focus on particular structure, as seen in his election requirement and in this rejection in which he asserted that it does not fit the phrase "expandable motion preserving device," does not address the issue of whether one of ordinary skill would understand from the specification how to perform or use the recited actions in the claimed methods.

Prior responses in this case have noted how the requirement for election among structures is not appropriate when methods are the claimed subject matter. MPEP 806.01 instructs that "[i]n passing upon questions of double patenting and restriction, it is the claimed subject matter that is considered and such claimed subject matter must be compared in order to determine the question of distinctness or independence" (emphasis added). Any election requirement for this case must identify independent and distinct methods, not structures having different characteristics, because it is not the structure(s) that are being claimed.

Respectfully, the Examiner's focus on structural embodiments in the application have obscured the fact that process claims are at issue. While the Examiner's requirement to choose a particular structure might be appropriate when the pending claims are directed to apparatus, it is

not appropriate for method claims. Steps recited in claim 1 (and claim 19) can be performed using the apparatus of Figures 1-7B or other apparatus disclosed in the application. Much of the process description in paragraphs 77-86 of the application (referring to numbers and drawings of Figures 1-7B) is very similar or identical to actions described in paragraphs 87-90 (referring to numbers and drawings of Figures 8A-12B). Paragraphs 107-108 refer to methods useful with "the expandable devices discussed herein," such as items 30, 130, 230 and 330.

Proper enablement exists when the application sets forth information sufficient to allow the person of ordinary skill in the art to create and use the claimed methods. The entire specification, not just that pertaining to an alleged species, must be considered in analyzing enablement. The language at issue ("placing a motion preserving device in a cavity of the expanded expandible device") was in claim 1 as originally filed. Merely the presence of a feature in the original claim language can enable that feature, MPEP 2164, and in this case there is also related disclosure in the specification of insertion of a motion preserving device within an expanded expandable device.

In *Callicrate v. Wadsworth Mfg., Inc.*, 427 F.3d 1361, 1373-74 (Fed. Cir. 2005), the Federal Circuit found that background disclosures in a parent application provided enough information by themselves to enable a claim feature, so that a later claim was entitled to the parent's filing date. If background information alone can enable a claim feature, then certainly inventive information relating to an alleged different species and recited in the original language of claim 1 must be used in considering enablement.

The Claims Meet the Enablement Requirement

The Examiner examined the pending method claims with reference to only one device embodiment. That embodiment is referred to in Figures 1-7A, with Figures 1-2, 4A-4B, 5A-5B, 6A-6B and 7A-7B showing all or part of that device embodiment (see, e.g., paragraphs 13-14 and 16-19 of the specification), and Figures 3A-3B showing an intervertebral space prepared for that device embodiment (see, e.g., paragraph 15). Along with the description of that device embodiment, paragraphs 77-86 discuss methods for using that device and additional disclosure. Paragraph 112 includes discussion of inserting a motion preserving device, and the specification teaches one of ordinary skill that techniques for one type of expandable device are usable with other embodiments of expandable devices (see, e.g., paragraph 107).

As to claim 1, no question exists concerning enablement for "accessing a disc space between vertebral bodies," which is seen in all of Figures 3A-7B and an embodiment described in at least paragraph 77. The remaining actions recited in claim 1 will be discussed separately:

delivering an expandable device into the disc space in an unexpanded condition— This action is exemplified in Figures 4A and 4B, as well as several paragraphs in the text. These include paragraphs 9-10 ("The expandable device has an unexpanded configuration for delivery to the operative site in minimally invasive procedures . . ."; "the interbody fusion device is delivered and expanded with the delivery instrument to distract the disc space"), paragraphs 64-66 ("delivering the expandable devices to the operative site and expanding the expandable devices in situ," for example by a "balloon catheter-type instrument having an expandable distal portion about which a collapsed expandable device is positioned," via recited approaches and using the assistance of given viewing systems), and paragraphs 77-79 (reciting discectomy,

endplate and insertion location preparation, placing unexpanded expandable device on delivery instruments and inserting to the insertion locations). The person of ordinary skill in the art is told a way to deliver an expandable device into a disc space in an unexpanded condition, from initial access to and preparation of the site to using a delivery instrument to do the actual delivering.

expanding the expandable device with an expandable element to distract the disc space, said expandable element being a balloon and said expanding including inflating said balloon with fluid— Paragraphs 70-72 identify an embodiment of item 55 (see also Figures 1-2 and 5A-6B) as a "balloon-like structure" on a shaft through which "fluid or material can be supplied . . . to enlarge or inflate expandable element 55." A particular example in paragraph 72 is a high-pressure balloon catheter inflatable with air or saline. That disclosure implicitly teaches the person of ordinary skill a way to expand a balloon expandable element with fluid, and with the disclosure of positioning and securing a collapsed expandable device on the expandable element (e.g. paragraphs 65, 70 and 71), it is sufficient to enable one of ordinary skill to perform the recited action. But this action is also explicitly explained in paragraph 79: a fluid is "delivered to expandable elements . . . through a syringe or pump operable to provide sufficient pressure for distraction of the adjacent vertebrae. As the pressure and volume of the respective expandable elements . . . increase, [the] expandable devices . . . are gradually expanded . . . until the desired disc space D1 is achieved."

deflating said balloon and removing said balloon from said expandable device and said disc space— The brief description of Figures 6A-7B (paragraphs 18 and 19) address this action succinctly, noting that the figures show the delivery instrument collapsed or deflated (Figs. 6A-6B) and removed from the surgical site (Figs. 7A-7B). Paragraph 80 instructs one of

ordinary skill to deflate the expandable element (e.g. a balloon) and removed from the now-expanded devices 30, 130 in the disc space. Paragraph 86 describes an alternative procedure in which one balloon or other expandable element can be used sequentially for two expandable devices, which implies deflation and withdrawal of the expandable element from an expandable device prior to using it with a second expandable device.

placing a motion preserving device in a cavity of the expanded expandable device— "[A] motion preserving device can be inserted into the cavity of the expandable devices 230, 330, as discussed further below." (Paragraph 109) The specification instructs that techniques useful with devices 230, 330 are also applicable to "other expandable device embodiments discussed herein." (Paragraph 107) Those instructions and others link the action of placing a motion preserving device with the structure of Figures 1-7B to one of ordinary skill in the art, telling him or her how to perform and use the last-recited action in claim 1.

Moreover, as noted above it is incorrect to limit the part of the specification considered in an enablement analysis. Paragraph 112 describes and enables the action of placing a motion preserving device in an expanded expandable device. With the disclosure of the way to perform and use the rest of the actions recited in claim 1 found throughout the application (including Figures 1-7B and related text), claim 1 is fully enabled. Add to that the fact that the "placing" action was originally in claim 1 as filed, and the question of enablement disappears.

There is No "New Matter" in Claim 1

The Office Action further alleged that "said expandable element being a balloon and said expanding including inflating said balloon with fluid; deflating said balloon and removing said

balloon from said expandable device and said disc space" was "new matter." The stated basis for this rejection was the enablement requirement of Section 112, paragraph 1, but the phrase "new matter" seems to suggest that the written description requirement is referred to. Either way, these features of claim 1 were discussed above at length. That discussion establishes that that language is fully supported by the drawings and text of this application, both in terms of enablement and in terms of written description.

No Individual Allegations under Section 112 Exist Against Dependent Claims

The Office Action based its enablement and "new matter" rejections solely on features recited in claims 1 and 19. It's Section 112 rejections of the dependent claims must therefore be grounded in the same reasoning. Accordingly, in light of the discussion above, no Section 112 grounds remain for the rejection of the dependent claims.

The Teitelbaum Reference Does Not Anticipate Claims 19-27, 30, or 33

The Office Action also alleged that claims 19-27, 30 and 33 were anticipated by the Teitelbaum reference (US 6,582,467). As with the previous rejection, the Office Action gave nothing other than a conclusory statement about anticipation. It is "incumbent upon the Examiner to identify wherein each and every facet of the claimed invention is disclosed in the applied reference." *In re Levy*, 17 USPQ2d 1461, 1462 (Board of Pat. App. & Interf. 1990); 37 CFR 1.104(c)(2). This rejection does not give a *prima facie* case of anticipation, and it does not meet the formal requirements of the MPEP and the CFR for a rejection. "The goal of examination is to clearly articulate any rejection early in the prosecution process so that the

applicant has the opportunity to provide evidence of patentability and otherwise reply completely at the earliest opportunity." MPEP 706. This rejection does not adequately identify or clarify the issues, at least because it does not identify where in the reference each part of the recited method is. Applicant is placed in the position of having to guess what the Examiner might be referring to in the reference, and Applicant cannot fully and completely respond.

Applicant noted these deficiencies in responding to the first Office Action, but the burden to provide a proper anticipation rejection has not yet been met. As to the Office Action's note that no arguments were given to show patentability of claim 19 over Teitelbaum, the Examiner has the initial burden of showing a *prima facie* case of anticipation, and no response is necessary from the Applicant where such a case is not presented. *See, e.g., In re Oetiker*, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992) ("If examination at the initial stage does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of the patent.")

However, in the interest of moving this case along toward allowance, Applicant responds to the extent possible. Teitelbaum does not anticipate claim 19 at least because it does not show expanding the expandable device by expanding the expandable element to restore a disc space height, as recited in claim 19. The reference discloses preparing a disc space and adjacent vertebral endplates (column 4, lines 5-14), expanding the disc space with a balloon (column 4, lines 14-17), and placing a stiff plastic or metal delivery sheath in the disc cavity (column 4, lines 18-19; column 3, lines 55-57). An expandable cage mounted on a dual balloon is advanced through that stiff sheath, and expanded (column 4, lines 19-26). After expansion, the cage is packed with supporting bone or bone matrix material, and after that the stiff sheath is removed (column 4, lines 26-30).

Thus, Teitelbaum's method expands a disc space with one balloon, holds it open with a stiff sheath, and inserts a cage/balloon combination into the sheath. Expansion of the cage by its balloon does not restore a disc space height. Teitelbaum does not necessarily disclose restoration of a disc height, only that a disc space is expanded. Moreover, that expansion is not performed by the balloon with the cage. The balloon and cage combination remains inside the stiff sheath, and thus away from the vertebrae. In other words, the expansion of the cage cannot have any effect on the vertebrae, because the support sheath around it is holding the vertebrae away from it. The cage, packed with supporting material inside, only contacts the vertebrae after the sheath is withdrawn at the end of the procedure. Teitelbaum cannot be modified to use its cage/balloon combination to restore a disc height without fundamentally changing its operating principles, such as holding open the vertebrae with the supporting sheath.

It is noted that Teitelbaum asserts that its cage may be "expanded to come into apposition with endplates above and below [and] sharp barbs 12 protrude into the subcortical bone." Further, it suggests a design for its cage that "permit[s] the superior and inferior surfaces to flatten against the endplate[s]." See column 2, lines 45-53. This disclosure appears to be at odds with the method disclosures of columns 3 and 4, which describe expansion of the cage in the stiff sheath, and so the combination of those disclosures is likely inoperable. In any event, the noted language of column 2 does not disclose restoring a disc height. The first quotation notes insertion of barbs into bone, which does not move the bone much less restore a height, since the cage and its barbs move into and with respect to the bone. The second quotation concerning flattening indicates that pressures between the vertebrae and the cage, whether provided from within the cage or by the vertebrae, deform the cage rather than restoring a collapsed disc height.

Other embodiments in the Teitelbaum reference are even further away from the claimed methods. The self-expanding cages are not expanded by an expandable element as recited in claim 19, and the vertical cages similarly do not restore a disc height by their expansion via an expandable element.

Claims 20-33 are dependent from claim 19, and are allowable on that basis and/or on their own merit. For example, claim 26 recites that when expanded the expandable device has a first height adjacent one end and a second height adjacent the other end that is not equal to the first height. That feature is not seen in the Teitelbaum reference. Similarly, Teitelbaum does not show an expandable device tapered between its ends as recited in claim 27. Claim 33 recites positioning a motion preserving device in the expanded expandable device, and removing load supporting elements of the expanded expandable device. Teitelbaum discloses only fusion cages, and the only material in its expanded cage is bone or similar material for promotion of bone growth in the cage (see column 2, 57-62; column 4, lines 26-29). It does not and cannot show or suggest positioning a motion preserving device in an expanded expandable device. It also does not suggest removing anything from its expanded cage.

Claims 18 and 34 Should Not Be Withdrawn

Claims 18 and 34 should be included in examination, and their withdrawal by the Examiner is traversed. Traversal is based on the grounds already of record and stated above, including that the requirement for election focused on structure rather than on methods, as the claims recite. Reconsideration and rejoinder is respectfully requested.

Additional Remarks

The Office Action alleged that the "applicant argued that claim 1 requires a motion preserving device." That language is not in the Applicant's prior response. It was remarked that a reference did not show the placement of a motion preserving device in a cavity an expanded expandable device.

The fact that the "placing" language was in claim 1 as it was filed also suggests that the election requirement was not focused on "the invention," i.e. the claim language. "Species always refer the different embodiment of the invention." MPEP 806.04(e) (emphasis added). If a requirement for election of species is to be issued in this case, then one must differentiate species of methods, at least one of which was covered by claim 1. Rather, species were selected so that the action of placing a motion preserving device, indicated in Figures 33-34, was in a different species than the remainder of the actions in claim 1. Even if an argument that a broad claim is not enabled can be made, that suggests that there are no species of "the invention." It does not mean that species of "the invention" can be chosen so that no species embodies the entire subject matter of that broad claim.

Conclusion

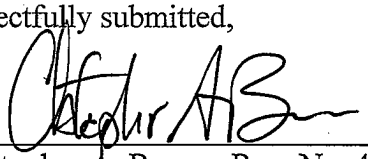
The pending claims are allowable for at least the above reasons. It should be understood that the above remarks are not intended to provide an exhaustive basis for patentability or concede the basis for the rejections in the Office Action, but are simply provided to overcome the rejections made in the Office Action in the most expedient fashion. The right to provide

additional remarks on these or different points, as may be necessary, is reserved. No narrowing of the claims is intended by any of the remarks herein, and none should be inferred.

The traverse concerning the prior election requirements is maintained, and no limitation on the claims should be inferred from those requirements. Several claims are denoted as "withdrawn." That indication is not an acknowledgement that such withdrawal is proper. All of the pending claims should be considered at least for the reasons given in prior filings in this case.

Examiner Snow is respectfully requested to reconsider this case and withdraw the present rejections. A Notice of Allowance in this case is respectfully solicited.

Respectfully submitted,



Christopher A. Brown, Reg. No. 41,642
Woodard, Emhardt, Moriarty,
McNett & Henry LLP
111 Monument Circle, Suite 3700
Indianapolis, IN 46204-5137
Tel.: (317) 634-3456

4002-3269. 548938